FEB 1 3 2006 W

DOCKET NO.: V0179.70001US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Erich Wanker et al.

Serial No.:

09/485,005

Confirmation No.:

1379

Filed:

September 11, 2000

For:

NOVEL METHOD OF DETECTING AMYLOID-LIKE

FIBRILS OR PROTEIN AGGREGATES

Examiner:

Gailene Gabel

Art Unit:

1641

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 7th day of February, 2006.

Melissa L. Barlow Lyons

MAIL STOP RCE

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

STATEMENT FILED PURSUANT TO THE DUTY OF DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. §1.114.

No fee or certification is required.

Serial No.: 09/485,005 -2 - Art Unit: 1641

Conf. No.: 1379

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified PTO/SB/08). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

- 1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
- 2. The enclosed form PTO-1449 (modified PTO/SB/08) be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
- 3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Serial No.: 09/485,005 - 3 - Art Unit: 1641

Conf. No.: 1379

Notwithstanding any statements by the Applicant, the Examiner is urged to form his or her own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,

By:

MaryDilys S. Anderson, Ph.D.

Reg. No. 52,560

Wolf, Greenfield & Sacks, P.C.

600 Atlantic Avenue

Boston, Massachusetts 02210-2206

Telephone: (617) 646-8000

Docket No.: V0179.70001US00

Date: February 7, 2006

x02/10/06x

OIP E	2006 W				
V .	, & /	_ J:C _	J DTO/SD/09)	APPLICATION NO.: 09/485,005	ATTY. DOCKET NO.: V0179.70001US00
THAT				FILING DATE: September 11, 2000	CONFIRMATION NO.: 1379
	RMATION DE SEMENT BY			APPLICANT: Erich Wanker et al.	
Sheet	1	of	3	GROUP ART UNIT: 1641	EXAMINER: Gailene Gabel

U.S. PATENT DOCUMENTS

Examiner's	Cite	U.S. Patent Docume	ent	Name of Patentee or Applicant of Cited	Date of Publication or Issue		
Initials #	No.	Number	Kind Code	Document	of Cited Document MM-DD-YYYY		
				-			

FOREIGN PATENT DOCUMENTS

Examiner's	Cite	Foreign Patent Document			Name of Patentee or Applicant of Cited	Date of Publication of	Translation
Initials #	No.	Office/ Country	Number	Kind Code	Document	Cited Document MM-DD-YYYY	(Y/N)

OTHER ART — NON PATENT LITERATURE DOCUMENTS of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
 , , _		BATES, G.P. et al., Transgenic models of Huntington's disease. Hum Mol Genet. 1997;6(10):1633-7.	
•		BECHER, M.W. et al., Intranuclear neuronal inclusions in Huntington's disease and dentatorubral and pallidoluysian atrophy: correlation between the density of inclusions and IT15 CAG triplet repeat length. Neurobiol Dis. 1998 Apr;4(6):387-97.	
		BEYREUTHER, K. et al., Alzheimer's disease. Tangle disentanglement. Nature. 1996 Oct 10;383(6600):476-7.	
		BOOTH, D.R. et al., Instability, unfolding and aggregation of human lysozyme variants underlying amyloid fibrillogenesis. Nature. 1997 Feb 27;385(6619):787-93.	
		BURKE, J.R. et al., Huntingtin and DRPLA proteins selectively interact with the enzyme GAPDH. Nat Med. 1996 Mar;2(3):347-50.	
		CAPUTO, C.B. et al., Amyloid-like properties of a synthetic peptide corresponding to the carboxy terminus of beta-amyloid protein precursor. Arch Biochem Biophys. 1992 Jan;292(1):199-205.	
		CAUGHEY, B. and CHESEBRO, B. Prion protein and the transmissible spongiform encephalopaties. Trends Cell Biol. 1997; 7: 56-62.	
		DE ROOIJ, K.E. et al., Subcellular localization of the Huntington's disease gene product in cell lines by immunofluorescence and biochemical subcellular fractionation. Hum Mol Genet. 1996 Aug;5(8):1093-9.	
		DIFIGLIA, M. et al., Aggregation of huntingtin in neuronal intranuclear inclusions and dystrophic neurites in brain. Science. 1997 Sep 26;277(5334):1990-3.	
		DIFIGLIA, M. et al., Huntingtin is a cytoplasmic protein associated with vesicles in human and rat brain neurons. Neuron. 1995 May;14(5):1075-81.	
		DUYAO, M.P. et al., Inactivation of the mouse Huntington's disease gene homolog Hdh. Science. 1995 Jul 21;269(5222):407-10.	
		GEORGALIS, Y. et al., Huntingtin aggregation monitored by dynamic light scattering. Proc Natl Acad Sci U S A. 1998 May 26;95(11):6118-21.	
		GLENNER, G.G. Amyloid deposits and amyloidosis. The beta-fibrilloses (first of two parts). N Engl J Med. 1980 Jun 5;302(23):1283-92 and 1333-1343.	
		GOLDBERG, Y.P. et al., Cleavage of huntingtin by apopain, a proapoptotic cysteine protease, is modulated by the polyglutamine tract. Nat Genet. 1996 Aug;13(4):442-9.	
		HDCRG. A novel gene containing a trinucleotide repeat that is expanded and unstable on Huntington's disease chromosomes. The Huntington's Disease Collaborative Research Group. Cell. 1993 Mar 26;72(6):971-83.	

P 4 P	HOLMBERG, M. et al., Spinocerebellar ataxia type 7 (SCA7): a neurodegenerative disorder with neuronal intranuclear inclusions. Hum Mol Genet. 1998 May;7(5):913-8.	
FEB 1 3 2006 2	HOOGEVEEN, A.T. et al., Characterization and localization of the Huntington disease gene	.,
EFD :	product. Hum Mol Genet. 1993 Dec;2(12):2069-73.	
النضا	IGARASHI, S. et al., Suppression of aggregate formation and apoptosis by transglutaminase	
THAD GURE	inhibitors in cells expressing truncated DRPLA protein with an expanded polyglutamine stretch. Nat Genet. 1998 Feb;18(2):111-7.	
	IKEDA, H. et al., Expanded polyglutamine in the Machado-Joseph disease protein induces cell	
	death in vitro and in vivo. Nat Genet. 1996 Jun;13(2):196-202.	
	JARRETT, J.T. and LANSBURY, P.T. Seeding "one-dimensional crystallization" of amyloid: a	
	pathogenic mechanism in Alzheimer's disease and scrapie? Cell. 1993 Jun 18;73(6):1055-8.	
	KALCHMAN, M.A. et al., HIP1, a human homologue of S. cerevisiae Sla2p, interacts with	
	membrane-associated huntingtin in the brain. Nat Genet. 1997 May;16(1):44-53.	
	KALCHMAN, M.A. et al., Huntingtin is ubiquitinated and interacts with a specific ubiquitin-	
	conjugating enzyme. J Biol Chem. 1996 Aug 9;271(32):19385-94.	
	LI, XJ. et al., A huntingtin-associated protein enriched in brain with implications for pathology.	
	Nature. 1995 Nov 23;378(6555):398-402.	
	LIM, K. et al., Three-dimensional structure of Schistosoma japonicum glutathione S-transferase	
	fused with a six-amino acid conserved neutralizing epitope of gp41 from HIV. Protein Sci. 1994 Dec;3(12):2233-44.	
	MATILLA, A. et al., The cerebellar leucine-rich acidic nuclear protein interacts with ataxin-1.	
	Nature. 1997 Oct 30;389(6654):974-8. Erratum in: Nature 1998 Feb 19;391(6669):818.	
	ONODERA, O. et al., Toxicity of expanded polyglutamine-domain proteins in Escherichia coli.	
	FEBS Lett. 1996 Dec 9;399(1-2):135-9.	
	PAULSON, H.L. et al., Intranuclear inclusions of expanded polyglutamine protein in	
	spinocerebellar ataxia type 3. Neuron. 1997 Aug;19(2):333-44.	
	PERUTZ, M.F. et al., Glutamine repeats as polar zippers: their possible role in inherited	
	neurodegenerative diseases. Proc Natl Acad Sci U S A. 1994 Jun 7;91(12):5355-8.	"
	PORTERA-CAILLIAU, C. et al., Evidence for apoptotic cell death in Huntington disease and	
	excitotoxic animal models. J Neurosci. 1995 May;15(5 Pt 2):3775-87.	
	PRUSINER, S.B. et al., Scrapie prions aggregate to form amyloid-like birefringent rods. Cell. 1983	
	Dec;35(2 Pt 1):349-58.	
	ROIZIN, L. et al., Neuronal nuclear-cytoplasmic changer in Huntington's chorea. J. Neurol. Sci.	
	1983; 61: 37-47.	
	ROOS, R.A.C. et al., Nuclear membrane indentations in Huntington's chorea. J Neurol Sci. 1983	
	Sep;61(1):37-47.	
	ROSS, C.A. When more is less: pathogenesis of glutamine repeat neurodegenerative diseases.	
	Neuron. 1995 Sep;15(3):493-6.	
	RUBINSZTEIN, D.C. et al., Phenotypic characterization of individuals with 30-40 CAG repeats in	
	the Huntington disease (HD) gene reveals HD cases with 36 repeats and apparently normal elderly	
	individuals with 36-39 repeats. Am J Hum Genet. 1996 Jul;59(1):16-22.	
	SATHASIVAM, K. et al., Identification of an HD patient with a (CAG)180 repeat expansion and	
	the propagation of highly expanded CAG repeats in lambda phage. Hum Genet. 1997	
	May;99(5):692-5.	
•	SCHATZ, P.J. Use of peptide libraries to map the substrate specificity of a peptide-modifying	
	enzyme: a 13 residue consensus peptide specifies biotinylation in Escherichia coli. Biotechnology	
-	(N Y). 1993 Oct;11(10):1138-43.	
	SCHERZINGER, E. et al., Huntingtin-encoded polyglutamine expansions form amyloid-like protein	
	aggregates in vitro and in vivo. Cell. 1997 Aug 8;90(3):549-58.	
	SHARP, A.H. et al., Widespread expression of Huntington's disease gene (IT15) protein product.	
	Neuron. 1995 May;14(5):1065-74.	
	SITTLER, A. et al., Alternative splicing of exon 14 determines nuclear or cytoplasmic localisation of fmr1 protein isoforms. Hum Mol Genet. 1996 Jan;5(1):95-102.	
	SITTLER, A. et al., SH3GL3 associates with the Huntingtin exon 1 protein and promotes the	
	formation of polygln-containing protein aggregates. Mol Cell. 1998 Oct;2(4):427-36.	
1	SKINNER, P.J. et al., Ataxin-1 with an expanded glutamine tract alters nuclear matrix-associated	
	I SKINNER PI et al. Atavin-I with an evnanded dilitamine tract alters nicclear matrix-associated. I	

OIPE 4AA		
CER 1 3 2006 W	SMITH, D.B. et al., Single-step purification of polypeptides expressed in Escherichia coli as fusions with glutathione S-transferase. Gene. 1988 Jul 15;67(1):31-40.	
	TELLEZ-NAGEL, I. et al., Studies on brain biopsies of patients with Huntington's chorea. J Neuropathol Exp Neurol. 1974 Apr;33(2):308-32.	
TRADA	TOWBIN, H. et al., Electrophoretic transfer of proteins from polyacrylamide gels to nitrocellulose sheets: procedure and some applications. Proc Natl Acad Sci U S A. 1979 Sep;76(9):4350-4.	·
	TROTTIER, Y. et al., Cellular localization of the Huntington's disease protein and discrimination of the normal and mutated form. Nat Genet. 1995 May;10(1):104-10.	
	VONSATTEL, JP. et al., Neuropathological classification of Huntington's disease. J Neuropathol Exp Neurol. 1985 Nov;44(6):559-77.	
	WANKER, E.E. et al., HIP-I: a huntingtin interacting protein isolated by the yeast two-hybrid system. Hum Mol Genet. 1997 Mar;6(3):487-95.	

EXAMINER:	DATE CONSIDERED:

[NOTE – No copies of U.S. patents, published U.S. patent applications, or pending, unpublished patent applications stored in the USPTO's Image File Wrapper (IFW) system, are included. See 37 CFR §1.98 and 12870G163. Copies of all other patent(s), publication(s), unpublished, pending U.S. patent applications, or other information listed are provided as required by 37 CFR §1.98 unless 1) such copies were provided in an IDS in an earlier application that complies with 37 CFR §1.98, and 2) the earlier application is relied upon for an earlier filing date under 35 U.S.C. §120.]

[#] EXAMINER: Initial if reference considered, whether or notcitation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

^{*}a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. ___, filed ___, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).